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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/043,639   | 01/09/2002  | Patricia Sarcabal    | CHEP:004US              | 6528             |
| 7590   | 11/01/2006  |                      | EXAMINER                |                  |
| Mark B. Wilson<br>Fulbright & Jaworski L.L.P.<br>Suite 2400<br>600 Congress Avenue<br>Austin, TX 78701 |             |                      | FRONDA, CHRISTIAN L     |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 1652                    |                  |
|  |             |                      | DATE MAILED: 11/01/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/043,639             | SARCABAL ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Christian L. Fronda    | 1652                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 17 August 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 33-51,53-67,82-84 and 86-88 is/are pending in the application.
  - 4a) Of the above claim(s) 33-49 is/are withdrawn from consideration.
- 5) Claim(s) 50,51,53-67,86 and 87 is/are allowed.
- 6) Claim(s) 82-84 and 88 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03 January 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Claims 33-51, 53-67, 82-84, and 86-88 are pending in the instant application. Claims 33-49 have been previously withdrawn from consideration.
2. Claims 50, 51, 53-67, 82-84, and 86-88 are under consideration in this Office Action.
3. The rejection of claims 50, 51, and 53-67 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' amendment to the claims and arguments filed on 08/17/2006.
4. The rejection of claim 64 under 35 U.S.C. 112, first paragraph, for lacking enablement has been withdrawn in view of applicants' amendment to the claim and arguments filed on 08/17/2006.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 82-84 and 88 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process using an expression vector comprising a recombinant nucleic acid encoding a glycerol dehydrates having at least 90% amino acid identity with SEQ ID NO: 6 or SEQ ID NO: 7, a recombinant nucleic acid encoding a dimeric protein comprising a first polypeptide that has at least 90% amino acid identity to SEQ ID NO: 6 and a second polypeptide that has at least 90% amino acid identity to SEQ ID NO: 7, or a recombinant nucleic acid that has at least 90% nucleotide identity to SEQ ID NO: 4 and encodes a 1,3-propanediol dehydrogenase comprising an amino acid sequence of at least 90% amino acid identity to SEQ ID NO: 8; does not reasonably provide enablement for the full scope of the recited method encompassing any expression vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants' arguments filed

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08/17/2006 have been fully considered but are not persuasive for reasons of record as further explained below.

In response to applicant's arguments, the recitation that the polypeptide comprises at least 90% amino acid identity with SEQ ID NO: 6 or SEQ ID NO: 7, a recombinant nucleic acid encoding a dimeric protein comprising a first polypeptide comprising at least 90% amino acid identity to SEQ ID NO: 6 and a second polypeptide comprising at least 90% amino acid identity to SEQ ID NO: 7, or a recombinant nucleic acid that has at least 90% nucleotide identity with SEQ ID NO: 4 and encodes a 1,3-propanediol dehydrogenase comprising an amino acid sequence of at least 90% amino acid identity to SEQ ID NO: 8 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Thus, the nature and breadth of the claims encompass any process comprising preparation of any expression vector to be used in the production of the recited glycerol dehydratase. The specification provides guidance and examples for making a recombinant nucleic acid encoding a glycerol dehydratase having the amino acid sequence of SEQ ID NO: 6 or SEQ ID NO: 7, a recombinant nucleic acid encoding a dimeric protein comprising a first polypeptide that has the amino acid sequence of SEQ ID NO: 6 and a second polypeptide that has the amino acid sequence of SEQ ID NO: 7, and a recombinant nucleic acid comprising SEQ ID NO: 4 and encodes a 1,3-propanediol dehydrogenase comprising the amino acid sequence SEQ ID NO: 8, where the specification discloses nucleotide sequences of SEQ ID NOs: 1-5.

However, the specification does not provide prediction, guidance, and working examples using any expression vector to be used in the recited method. Thus, an undue amount of experimentation must be performed to search, screen, and make any expression vector that can be used in the recited method. Searching and screening for the claimed invention is not guidance for making the invention. Furthermore, searching and screening for the claimed invention is outside the realm of routine experimentation.

The examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequences of the recombinant nucleic acids that can be cloned into the recited vector and used in the recited method to make the claimed glycerol dehydratase. Without such guidance, the amount of experimentation left to those skilled in the art to make the invention is undue.

Amending the claims to recite an expression vector comprising a recombinant nucleic acid encoding a glycerol dehydratase having at least 90% amino acid identity with SEQ ID NO: 6 or SEQ ID NO: 7, a recombinant nucleic acid encoding a dimeric protein comprising a first

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polypeptide that has at least 90% amino acid identity to SEQ ID NO: 6 and a second polypeptide that has at least 90% amino acid identity to SEQ ID NO: 7, or a recombinant nucleic acid that has at least 90% nucleotide identity to SEQ ID NO: 4 and encodes a 1,3-propanediol dehydrogenase comprising an amino acid sequence of at least 90% amino acid identity to SEQ ID NO: 8 may overcome the rejection. Alternatively, amending the claim to recite that the vector of claim 61 is used in method step (a) of claim 82 may overcome the rejection.

### ***Conclusion***

7. Claims 50, 51, 53-67, 86, and 87 are allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). CLF